focus on the path of the vagus nerve, not the human being to whom it belonged. Early in our training, bending over our cadavers, we learned to silence a part of ourselves. We learned the power of humor as a means of avoiding hard conversations about more complicated feelings. Often we kept those feelings to ourselves, rarely giving voice to them as we proceeded through far more challenging situations during our clerkships — a newly diagnosed lung cancer, a 2-year-old with an inoperable and therefore fatal brain tumor, a young man with quadriplegia from diving into shallow water. We discussed the medical management and the complications in detail and with intense care, but we could not give voice to the feelings these events evoked, often reducing them, in the formal case presentation, to the single word "unfortunate."

And because we cannot comfortably express these feelings, sometimes we put them away forever or feel incompetent and overwhelmed when we do try to express them. Perhaps if we could discuss this part of our practice lives as easily as we discuss a diagnostic dilemma or the proper management of a complex case, we might create a culture that supports and nourishes us as we try to come to terms with experiences that are part of our daily lives. Being able to communicate more honestly with each other might help us to do so with our patients as well. How different might those codes have felt if, at the end, having declared, "The code is called," the resident then said, "Let's have a moment of silence to honor this life."

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How do you deal with the emotionally challenging aspects of clinical care?

Perspective FORUM

We invite readers to respond to The Code in an online Perspective Forum with Dr. Treadway, at www.nejm.org. New comments and responses from Dr. Treadway will continue to be posted through October 10.

Cases in Vaccine Court — Legal Battles over Vaccines and Autism

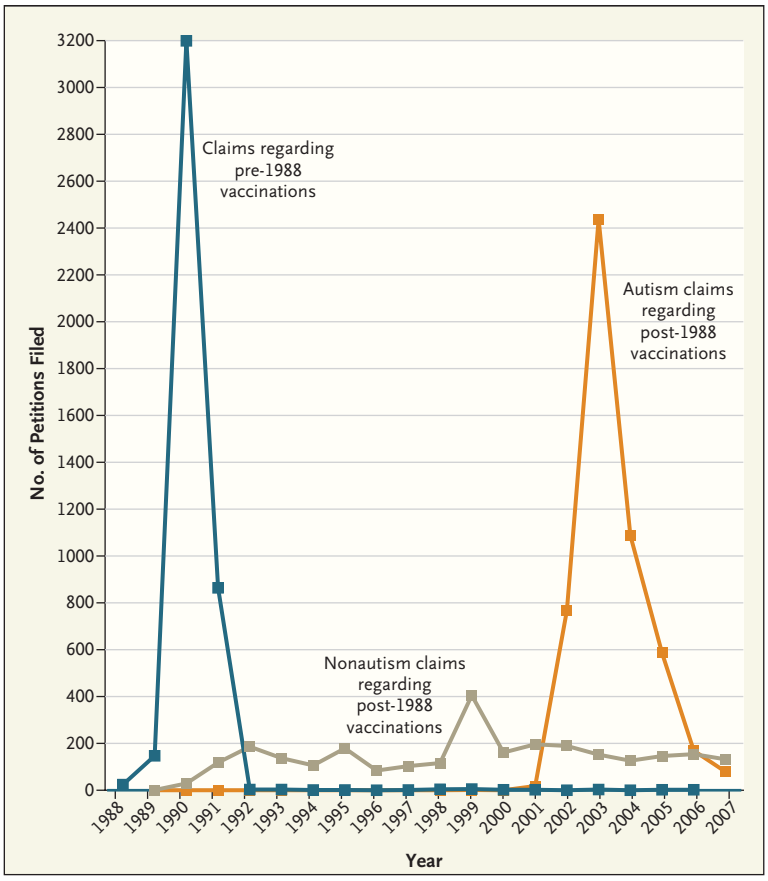
Stephen D. Sugarman, J.D.

Related article, page 1281

Do childhood vaccines cause autism? This scientific question has now become a legal one — perhaps inevitable in our society. Some families with autistic children are pursuing legal channels in an effort to prove that vaccines are responsible for their children's condition. Most of them allege that the cause is the mercury-containing preservative thimerosal, which was formerly used in many vaccines in the United States and elsewhere. Others argue that the culprit is the measles, mumps, and rubella (MMR) vaccine itself or perhaps the vaccine in combination with thimerosal.

Although most experts have concluded that there is no proof of a causal tie between autism and thimerosal or the MMR vaccine, some doctors and scientists, some groups representing families with autistic children, and many parents fervently believe there is a connection. Claimants not only want to prove that the federal government, the Institute of Medicine, vaccine makers, and mainstream science are wrong; they also want money. A child with autism is likely to require extraordinarily expensive services — and to have very limited employment prospects in adulthood. Besides, many parents of autistic children may feel better psychologically if they can blame profit-seeking drug companies for their children's problems.

More than 5000 such families



Claims Filed with the Vaccine Injury Compensation Program, 1989–2007.

Post-1988 vaccinations are those that occurred on or after October 1, 1988; pre-1988 vaccinations are those that occurred before that date. Data are from the Health Resources and Services Administration.

have filed claims with the federal Vaccine Injury Compensation Program (VICP) (see graph).[1] This legislation was adopted by Congress in 1988 in response to a somewhat similar scare over the pertussis portion of the diphtheria–pertussis–tetanus (DPT) vaccine. Alerted to a possible link by British researchers, many observers feared that the vaccine was causing some children grave neurologic harm — claims that were later generally discredited. Yet the alarm was so great that droves of British families refused the pertussis vaccine, substantial numbers of children became ill with whooping cough, and some 70 children died. In the United States, several parents sued the manufacturers of DPT vaccines. Even though most public health officials believed that the claims of side effects were unfounded, some families won substantial awards from sympathetic juries who were convinced otherwise. As a result, most companies making the DPT vaccine ceased production, and the remaining major manufacturer threatened to do so. Health officials feared the loss of herd immunity, and Congress responded by creating the VICP.

This program provides compensation to children who have serious adverse effects from any childhood vaccine. The compensation covers medical and related expenses, lost future income, and up to $250,000 for pain and suffering. The funding for paying successful claims regarding vaccines administered before 1988 came from the U.S. Treasury. For claims regarding later vaccinations, funding comes from a patient fee of 75 cents per vaccination. The VICP trust fund currently contains more than $2 billion. About 7000 claims have been filed for adverse effects other than autism, and so far about 2000 have resulted in compensation, in amounts averaging about $850,000. Approximately 700 claims remain unresolved, since the VICP frequently takes more than 2 years to process a petition.

To win a VICP award, the claimant does not need to prove everything that is required to hold a vaccine maker liable in a product liability lawsuit. But a causal connection must be shown. If medical records show that a child had one of several listed adverse effects within a short period after vaccination, the VICP presumes that it was caused by the vaccine (although the government can seek to prove otherwise). An advisory committee helps to amend the list of adverse effects as the consensus view changes with the availability of new studies. If families claim that a vaccine caused an adverse effect that is not on the list, the burden of proof rests with them. Autism is not on the list for any vaccine, and the VICP has rejected about 300 such claims outright.

But thousands of autism claims are pending. In 2002, to resolve such claims more expeditiously, the VICP announced that some test cases would examine the gen-

eral causation question, putting aside the question of harm to any particular child. Although this process was supposed to take only 2 years, the first of nine test cases was heard just this past summer, with many witnesses testifying for each side. A special section of the U.S. Court of Federal Claims administers the VICP, and judges running this so-called Vaccine Court are not expected to begin to decide these cases until 2008. Department of Justice lawyers appear in opposition to the claimants.

In the VICP context, proof of causation does not need to be shown to the extent of what some might call scientific certainty. Rather, it suffices to prove causation according to the civil-law standard of "the preponderance of the evidence," showing that causation is "more likely than not." Although proving a mere possibility won't suffice, proof "beyond a reasonable doubt" is not required.

If the petitioners lose in the VICP process, their quest for compensation does not necessarily end there. Although persons claiming vaccine-related injuries are supposed to seek a determination through the VICP process first, anyone who is dissatisfied with the result can bring a regular lawsuit alleging that a product is defective, and the named defendant can potentially be found liable. To win such a case, a claimant would have to persuade a jury that the vaccine not only harmed an individual child but also had a defective design or failed to carry adequate warnings.

By offering a no-fault alternative remedy that includes a chance to be heard, the VICP was meant to discourage litigation as a way of ensuring vaccine availability. Although some families have complained bitterly about the VICP, few who have been denied compensation by the program have then sued. The autism cases, however, may play out differently if, as many predict, VICP judges reject the claims on the grounds of insufficient proof of general causation. Not only do families with autistic children have support groups and organized lawyers behind them, but they also have the backing of several prominent senators and congressional representatives.

Indeed, several families have already tried to bypass the VICP process, going directly to court with creative legal arguments. Some assert that thimerosal is not included in the legal definition of a "vaccine" or that it represents an "adulteration," so their claims should be exempt from the VICP process. The government and vaccine makers argue that such claimants must file first with the VICP, and so far they are generally winning on this issue. Other claimants are having better luck with different end-run approaches — suing companies that make thimerosal, for instance, arguing that the preservative suppliers are not vaccine makers; filing class-action suits on behalf of parents; or demanding medical monitoring for vaccinated children who do not yet show signs of autism. Even in instances in which claimants are making modest procedural headway, such lawsuits seem a long way from resolution.

In Britain, meanwhile, an interesting counter-story is unfolding. Physician–researcher Andrew Wakefield and two of his colleagues are in the middle of a hearing before Britain's General Medical Council, which is investigating charges that could cost the doctors their medical licenses. In 1998, this trio (with many others) published an article indicating that there were possible harms from the MMR vaccine[2] (thimerosal was not blamed, since it was not used in the British vaccine); the journal has since stated that it should not have published the article in the way that it did,[3] and nearly all the authors have retracted their initial interpretation of their findings.[4] The case against Wakefield and his colleagues is based primarily on accusations about the way the research was conducted, and one charge is that Wakefield failed to disclose his connections to lawyers involved in vaccine litigation. The hearing is expected to last several months. Because American lawyers are now claiming that their clients' harms were caused by either thimerosal or the MMR vaccine or both in combination, whatever the conclusion of the Wakefield hearing, it is unlikely to end the U.S. battles over vaccines and autism.

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1. Department of Health and Human Services. National Vaccine Injury Compensation Program (VICP). Rockville, MD: Health Resources and Services Administration. (Accessed September 6, 2007, at http://www.hrsa.gov/vaccinecompensation/.)
2. Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. Lancet 1998;351:637-41.
3. Horton R. A statement by the editors of The Lancet. Lancet 2004;363:820-1.
4. Murch SH, Anthony A, Casson DH, et al. Retraction of an interpretation. Lancet 2004; 363:750.